DEMOCRACY FORWARD FOUNDATION

April 2, 2020

Hon. Paul W. Grimm
United States District Judge
6500 Cherrywood Lane
Greenbelt, MD 20770

RE: American Academy of Pediatrics, et al., v. FDA (No. 8:18-cv-883-PWG)

Dear Judge Grimm,

Plaintiffs write in response to Defendants' letter describing their planned request for an indicative ruling. Doc. No. 175. Given the unprecedented circumstances and all parties' interest in avoiding unnecessary litigation at this difficult time, Plaintiffs are not opposing Defendants' motion, but would likely oppose requests for further similar relief.

That said, Plaintiffs do wish to register their concern with the length and breadth of the extension Defendants propose. Plaintiffs understand FDA's plan to be to exempt for an additional 120 days all deemed products that were on the market before August 8, 2016 from the Tobacco Control Act's premarket authorization requirement, except for those prioritized for enforcement before May 12, 2020 in Parts D.1 through D.3 of the January 2020 Guidance.[1] This extension would accommodate not only manufacturers that were genuinely working toward filing premarket tobacco applications and substantial equivalence reports, but also those that never intended to file applications, or planned to file entirely incomplete applications or reports simply to keep their products on the market during FDA's review. It also grants a delay without regard to whether a manufacturer is now engaged in active research or laboratory analysis that has been disrupted, and it ignores the fact that manufacturers have known for 4 years that these applications were going to be due at some time. It would thus reward dilatory manufacturers engaged in avoidance of their statutory obligations, where more targeted relief could prevent those manufacturers from receiving a windfall exemption.

The 120-day extension allows the covered products to remain on the market without threat of enforcement through September 9, 2020. Although Plaintiffs recognize that COVID-19 poses unique issues, it seems premature to extend the exemption so far into the future at this time for

[1] *See* FDA, "Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization—Guidance for Industry" (January 2020) at 18-27, https://www.fda.gov/media/133880/download.

this particular industry, especially in light of the fact that the products that are subject to the review continue to be sold to consumers, and in particular young people.

These concerns are especially heightened because, according to the FDA itself, both e-cigarettes and combustible cigarettes may increase the risk of serious complications from COVID-19.[2] FDA's extension results in the continuation and proliferation of products with unknown risks on the market, in direct conflict with the Tobacco Control Act.

Accordingly, Plaintiffs would likely oppose further similar extensions, and, if further relief is absolutely necessary, instead respectfully encourage FDA to limit any requested future relief to manufacturers that can show that they would have been on track to file the relevant application by May 12 but for the COVID-19 emergency and the restrictions that it has required.

Respectfully submitted,

/s/ Jeffrey B. Dubner
Jeffrey B. Dubner

[2] *See, e.g.*, Anna Edney & Angelica LaVito, *Vaping Could Compound Health Risks Tied to Virus, FDA Says*, Bloomberg, Mar. 27, 2020, https://www-bloomberg-com.cdn.ampproject.org/c/s/www.bloomberg.com/amp/news/articles/2020-03-27/vaping-could-increase-health-risks-tied-to-covid-19-fda-says.